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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,680	BLAIR ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to paper filed 18 October 2004.

Claims 1- 23 are pending.

Claim Objections

Claims 12 and 23 are objected to because of the following informalities: The claims refer to a method and the claim that it depends from is not a method. It appears that they are intended to depend from claims 11 and 22, respectively, and will be treated as such. Appropriate correction is required.

New Rejection

New Matter

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 13 recite the limitation "high-

volume". This limitation is not apparent in the specification. The specification recites "high throughput" in several places (see for example page 1, line 26).

Rejections Withdrawn

Claim Rejections - 35 USC § 103

Claims 5, 6, 16, and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine et al. and Gibbs.

The rejection is withdrawn Haseltine et al. is no longer the "base" reference.

Claims 1- 4, 10, 11, 13- 15, 21, and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu et al.

The rejection is withdrawn Haseltine et al. is no longer the "base" reference.

Claims 9- 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu et al., as applied to claims 1- 4, 10, 11, 13- 15, 21, and 22 above, and and Shi et al.

The rejection is withdrawn Haseltine et al. is no longer the "base" reference.

New Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1, 4, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen *et al.* (from IDS, 1994 Journal of Virology Vol. 68, pages 654-660).

The claims are drawn to replication competent HIV-1 viral vector in which a non-essential region for viral replication has been replaced by a reporter gene. The further limitation "suitable for use" has been partly addressed in the new matter rejection but is only an **intended use limitation** and without specific structural limitations in the claims, this limitation does not carry any weight in terms of patentability.

Chen *et al.* teach a replication competent HIV-1 viral vector in which *nef,* a non-essential region for viral replication, has been replaced by a luciferase reporter gene which when expressed from the nef region is a sensitive and quantitative marker (page 654, column 2, last full paragraph).

Thus, Chen *et al.* anticipate the claimed invention.

Claims 1, 4, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Haseltine *et al.*

Claim 1 was amended to include the limitation "suitable for use in a high volume anti-viral assay" Claims 2, 4, 10, and 11 depend from claim 1. Added term is now rejected as new matter and even if amended to "high throughput" as disclosed in the specification will still be subject to rejection over this prior art for the following reasons: After reconsideration the limitation is considered to be an intended use and not required for the claim. Furthermore, there is no structural limitation in the claim that is

commensurate in scope with applicant's arguments that caused the rejection to be withdrawn. For these reasons the rejection is reinstated

Haseltine *et al.* teaches a replication competent HIV-1 virus with a deletion in a non-essential region of the virus and a heterologous DNA inserted. In this case the heterologous DNA is a reporter gene to trace HIV replication or monitor the effects of anti-HIV drugs in a screening assay (abstract and page 4 and 5).

Thus, Hasteltine *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

Claims 1, 5-9, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* as applied to claims 1, 4, and 10 above, and further in view of Gibbs *et al.* (from IDS, cited in previous action), Shi *et al.* (cited in previous action), Collman *et al.* (cited in previous action), or Li *et al.* (cited in previous action).

The claims are drawn to replication competent HIV-1 viral vector in which a non-essential region for viral replication has been replaced by a reporter gene. The further limitation "suitable for use" has been addressed in the new matter rejection but is only an **intended use limitation** and without specific structural limitations in the claims, this limitation does not carry any weight in terms of patentability. The claims are also drawn to different viral clones.

Chen *et al.* teach a replication competent HIV-1 viral vector in which *nef,* a non-essential region for viral replication, has been replaced by a luciferase reporter gene (page 654, column 2, last full paragraph).

Chen *et al.* do not teach that the vpr region is non-essential or the other viral clones.

Gibbs *et al.* teach a proviral clone pNL4-3 and that vpr is a non essential region and can be deleted, figures 2 and 3 and Discussion.

Shi *et al.* teach a similar viral vector using the proviral clone HIV-I Lai.

Collman *et al.* teach an infectious clone of HIV-1, p89.6 which has a novel tropism.

Li *et al.* teach an infectious proviral clone of pYU-2.

Each of the references teaches an infectious HIV-1 clone. One of ordinary skill in the art at the time of invention would have known that the assay of Chen *et al.* could be used with other proviral clones to study other clones ability to infect cells or their tropism. One of ordinary skill in the art at the time of invention would have been motivated to do so because the other infectious clones could be modified for use in the assay of Chen *et al.*

It would have been *prima facie* obvious to one skilled in the art to modify the vector of Chen *et al.* with other infectious proviral clones or appropriate cell lines to study infection with the expectation of success.

Claims 1-3, 11-14, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., Haseltine et al. and Liu et al.

Chen et al. teach a viral vector essentially as claimed as discussed above.

Chen et al. do not teach renella luciferase reporter gene or test compound assay.

Liu et al. teach an improved reporter gene that is secreted and allows for increased sensitivity and secreted reporter genes offer the advantages of being able to monitor over time without cell or tissue destruction (page 153).

Haseltine et al. (discussed above) teach a viral vector similar to Chen et al comprising a reporter gene inserted in a non-essential region to serve as a marker for gene expression and an assay to test compounds for antiviral activity.

One of ordinary skill in the art at the time of invention it would have been motivated to modify the vector of Chen et al. with the improved luciferase reporter gene (Chen et al. uses a different luciferase gene) to gain the advantages as taught by Liu et al. At the time of invention it would have been obvious to use the modified virus in the assay of Haseltine et al. (as discussed above) for the benefit of ease of screening of compounds that could be used as antivirals. One of ordinary skill in the art at the time of invention would have known that the choice of cells would include those that can be infected by the virus or made to be infected because macrophage-tropic/non-syncytium-inducing (NSI) viruses use CCR5 as a receptor for cell entry.

The method claims only require contacting cells with a test compound that are infected or will be infected and comparing that to a control.

Thus, it would have been *prima facie* obvious to modify the virus of Chen et al. with an expectation of success of having a reporter gene that is easier to screen for test agents in the assay of Haseltine et al.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill
Patent Examiner
March 18, 2005

James C. Housel
3/2/05